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Attorneys for Plaintiffs and the Certified Classes

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

NEETA THAKUR, et al.,

Plaintiffs,

v.

DONALD J. TRUMP, et al.,

Defendants.

Case No. 3:25-cv-4737

DECLARATION OF MARCUS A. HORWITZ

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I, Marcus A. Horwitz, declare as follows:

1. I have personal knowledge of the facts contained in this declaration and, if called as a witness, could and would testify competently to those facts.

2. I am a Distinguished Professor of Medicine and of Microbiology, Immunology, and Molecular Genetics in the Department of Medicine at the University of California Los Angeles School of Medicine. A true and correct copy of my curriculum vitae is attached as **Exhibit A**.

3. I earned my A.B in Physics from Cornell University in 1968, and my M.D. from Columbia University College of Physicians and Surgeons in 1972. I subsequently trained in Internal Medicine and Infectious Diseases at the Albert Einstein College of Medicine. I served for two years as an Epidemic Intelligence Officer at the CDC and then trained in cellular physiology and immunology at The Rockefeller University. From 1980 to 1985, I was on the faculty of The Rockefeller University as an Assistant Professor and Associate Physician. In 1985, I joined the faculty of UCLA as a Professor of Medicine and of Microbiology, Immunology and Molecular Genetics, a position I held until 2011. I also served as Chief of the Division of Infectious Diseases at UCLA School of Medicine from 1985-92. I have held the position of Distinguished Professor of Medicine and of Microbiology, Immunology, and Molecular Genetics since 2011.

4. I am a fellow in the Infectious Diseases Society of America and a member of the American Society for Clinical Investigation. My awards include the Oswald Avery (formerly Squibb) Award from the Infectious Diseases Society of America and election to Fellowship in the American Association for the Advancement of Science.

5. My research has focused on intracellular parasitism, especially the immunobiology of the etiologic agents of Legionnaires' disease, leprosy, tuberculosis, and tularemia. In addition, in translational work, I have developed vaccines against Legionnaires' disease, tuberculosis, leprosy; the Tier 1 Select Agent Diseases tularemia, anthrax, plague and melioidosis; and a universal vaccine against COVID-19. Finally, in additional translational work, I have developed an ultra-short drug treatment regimen for treating tuberculosis that is currently in clinical trials. I

have authored more than 320 papers and abstracts including more than 150 peer-reviewed publications in scientific journals, and edited a book titled "Bacteria – Host Cell Interaction." I have 26 issued U.S. patents and numerous foreign patents on technologies developed in my laboratory. I have been a co-investigator or principal investigator on numerous projects funded through research grants from governmental and private sources, including 34 research grants from the National Institutes of Health ("NIH") since 1985.

6. Most of these research grants have been multi-year awards providing funds for 2, 3, 4 or 5 years. In my over 40 years of continuous NIH funding, I have never before received notice that NIH suspended grant funding for projects that I had been working on, until I received notice that NIH had suspended four of my projects' grants, including three which still had funds remaining. The three still-active grants and the impacts of their suspension are discussed in turn below.

Suspended Grant 1 – The TB Vaccine Project (Grant Number 1R01AI135631)

7. On November 29, 2017, NIH, through the National Institute of Allergy and Infectious Diseases, issued a Notice of Award for Grant Number 1R01AI135631-01, authorizing grant funding for the project for which I am Principal Investigator, titled "Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis" (hereafter, the "TB Vaccine Project"). The goal of the TB Vaccine Project was to identify a more effective vaccination against Tuberculosis. The Project Narrative for the TB Vaccine Project explained:

> Tuberculosis (TB) is one of the world's most important diseases, and a safe and effective vaccine against the causative agent *Mycobacterium tuberculosis (Mtb)* that is more potent than the currently available only partially effective *M. bovis* strain *Bacille Calmette-Guerin* (BCG) vaccine is sorely needed. It is generally acknowledged that both an improved replacement vaccine for BCG and a potent heterologous booster vaccine are needed in the fight against TB. The purpose of this project is to optimize and conduct advanced proof-of-concept studies in small animals and non-human primates (NHP) of a second-generation heterologous multiantigenic recombinant attenuated *Listeria monocytogenes*-vectored vaccine against TB.

8. A true and correct copy of the TB Vaccine Project Narrative is attached as **Exhibit B**. A true and correct copy of NIH's November 2017 Notice of Award for the TB Vaccine Project

is attached as **Exhibit C**. That Notice of Award authorized funding for five years of work on the TB Vaccine Project, from December of 2017 through November of 2022, for a total award of $5,424,173.

9. NIH issued further Notices of Award for the TB Vaccine Project, authorizing continued funding in November 2018, December 2019, and November 2020. True and correct copies of each of these Notices of Award are attached as **Exhibits D**, **E**, and **F** respectively. The TB Vaccine Project's work with primates was delayed during COVID-19, and as a result, the TB Vaccine Project obtained three No-Cost Time Extensions. True and correct copies of each of these No-Cost Time Extensions are attached as **Exhibits G**, **H**, and **I**. These No-Cost Time Extensions increased the TB Vaccine Project from five years to eight years, with the TB Vaccine Project's end date revised to November 30, 2025.

10. On August 1, 2025, I received an email from UCLA's Office of Contract & Grant Administration with the subject line "Grant Suspension Notice – Stop Work Order [PATS 20173817]". This email informed me that "UCLA has received a suspension notice from NIH-NIAID" for the TB Vaccine Project, and notified me that I must "***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***." (emphasis in original). A true and correct copy of this Stop Work Order is attached as **Exhibit J**. NIH's suspension of TB Vaccine Project suspended approximately $143,594 in unfunded award still outstanding to complete TB Vaccine Project's work.

11. I, my team, and the public interest have all suffered harm as a result of the TB Vaccine Project's grant funding suspension. First, while the live-animal component of the final definitive proof-of-concept vaccine study in non-human primates at the Texas Biomedical Research Institute (TBRI) was completed, we are unable to proceed further with analyzing bacterial read-outs, or study lung pathology and radiology (PET/CT), or analyze these data as a correlate of vaccine function. Therefore, despite completing the live-animal component of the final definitive vaccine efficacy study, we cannot uncover the extent to which the vaccine worked. Were that information available and the vaccine shown to be highly protective, as preliminary data suggests, we would have immediately begun plans to take the vaccine into

clinical trials. Our inability to do so potentially substantially delays development of a potent TB vaccine for which the primary purpose is to boost the immunity of the ~5 billion people in the world previously vaccinated with BCG and in whom most TB cases in the world develop. Second, our inability to complete the work and publish it hinders the career of the Project Scientist in my laboratory who developed this vaccine and the careers of our collaborators at TBRI. Third, the suspension of this study before the final results could be determined, at a cost to taxpayers of over $5.3 million dollars, constitutes a major waste of taxpayer funds.

Suspended Grant 2 – The Latent TB Treatment Project (Grant Number 1R01AI183978)

12. On February 27, 2024, NIH, through the National Institute of Allergy and Infectious Diseases, issued a Notice of Award for Grant Number 1R01AI183978-01 authorizing grant funding for the project for which I am Principal Investigator, titled "Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a Setting Mimicking HIV co-infection" (hereafter, the "Latent TB Treatment Project"). The goal of the Latent TB Treatment Project was to examine a short-term three-drug treatment regimen for latent tuberculosis infection ("LTBI"), leveraging the artificial intelligence-enabled parabolic response surface platform (AI-PRS) to determine whether this treatment prevents reactivation of tuberculosis. As explained in the Project Summary for the Latent TB Treatment Project:

> The great majority of people who are infected with *Mycobacterium tuberculosis* (Mtb) do not develop active disease but contain the bacterium in a dormant state [known as LTBI]… Many of these people reactivate tuberculosis (TB) later in life, often in association with an immunocompromised status, such as co-infection with HIV, immunotherapy for cancer or other diseases, aging, etc. An estimated 2 billion people on earth have LTBI and constitute a huge reservoir of people at risk of reactivation TB unless treated and the persistent Mtb state eliminated. Current treatment regimens for LTBI are long and burdensome, negatively impacting treatment completion. The study proposed herein seeks to examine a potentially much shorter regimen requiring as little as one or two weeks. If successful, and then replicated in humans, such a short term regimen could change clinical practice… If short term Clofazimine, Bedaquiline and Pyrazinamide treatment prevents reactivation TB, this study will pave the way for a definitive treatment-shortening trial of Clofazimine, Bedaquiline and Pyrazinamide in LTBI and potentially revolutionize the treatment of LTBI, hastening the elimination of the TB reservoir and subsequently TB.

13. A true and correct copy of the Project Summary for the Latent TB Treatment

Project is attached as **Exhibit K**. A true and correct copy of the NIH's February 2024 Notice of Award for the Latent TB Treatment Project is attached as **Exhibit L**. That Notice of Award authorized funding for nearly three years of work on the Latent TB Treatment Project, from March 2024 through January 2027. NIH's initial Notice of Award was superseded by a revised Notice of Award sent on May 30, 2024, which provided for total funding of $2,798,273 between March 2024 and January 2027. A true and correct copy of NIH's May 2024 Revised Notice of Award for the Latent TB Treatment Project is attached as **Exhibit M**.

14. NIH issued a further Notice of Award for the Latent TB Treatment Project, authorizing continued funding in February 2025. A true and correct copy of this Notice of Award is attached as **Exhibit N**.

15. On August 1, 2025, I received an email from UCLA's Office of Contract & Grant Administration with the subject line "Grant Suspension Notice – Stop Work Order [PATS 20240819]". This email informed me that "UCLA has received a suspension notice from NIH-NIAID" for the Latent TB Treatment Project, and notified me that I must "***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***." (emphasis in original). A true and correct copy of this Stop Work Order is attached as **Exhibit O**. NIH's suspension of Latent TB Treatment Project suspended approximately $2,333,898 in unfunded award still outstanding to complete Latent TB Treatment Project's work.

16. I, my team, and the public interest have all suffered harm as a result of the Latent TB Treatment Project's grant funding suspension. First, we are unable to continue to support the salary component of collaborating individuals at the Subaward site Texas Biomedical Research Institute (TBRI) including the two leading collaborating co-investigators, a Staff Scientist, a Post-doctoral fellow, and two technicians. Second, this significantly damages the career of the collaborating co-investigators, staff scientist, and especially the post-doctoral fellow as they are unable to complete and publish the work. Third, while we made impressive headway in performing initial work on pharmacodynamics and pharmacokinetics of these drugs, we are unable to complete this work in collaboration with another collaborating co-investigator and specialist in this area at another collaborating institution. Fourth, while we were close to

beginning the animal component of the studies using non-human primates (NHPs), and TBRI had identified and assigned primates for this purpose, we are now unable to begin this critical study which would have uncovered if this drug regimen has efficacy against LTBI. Such a result has the potential to revolutionize treatment of people with LTBI worldwide, of which there are approximately 2 billion, and in whom TB can reactivate at any point in their lives if not appropriately treated.

Suspended Grant 3 – The T7SS Drug Project (Grant Number 1R21AI185484)

17. On July 17, 2025, NIH, through the National Institute of Allergy and Infectious Diseases, issued a Notice of Award for Grant Number 1R21AI185484-01A1 authorizing grant funding for the project for which I am Principal Investigator, titled "Identification by High Throughput Screening of Inhibitors of the Mycobacterium tuberculosis ESX-1 and ESX-5 Type VII Secretion Systems – critical virulence determinants and novel drug targets" (hereafter, the "T7SS Drug Project"). The goal of the T7SS Drug Project was to identify promising lead compounds with the highest therapeutic ratio and study them to potentially develop a new class of antibiotics to treat tuberculosis. As explained in the Project Summary for T7SS Drug Project:

> Tuberculosis (TB) is a serious global health problem, causing ~10.6 million active cases and 1.3 million deaths/year. Better drugs are urgently needed to shorten the burdensomely long treatment course and to combat the global emergence of drug resistant strains of *Mycobacterium tuberculosis* (Mtb), the causative agent. Attractive and novel targets not previously exploited for new drug development are the newly identified Type 7 Secretion Systems (T7SSs), designated ESX-1 to ESX-5, that transport factors through the Mtb hydrophobic cell wall that are essential to Mtb viability…These studies will identify the most promising lead compounds with the highest therapeutic ratio for further development. Such compounds will serve as vital tools for additional studies of the role of T7SS in Mtb pathogenesis as well as lead compounds for development of a new class of antibiotics to treat TB.

18. A true and correct copy of the Project Summary for T7SS Drug Project is attached as **Exhibit P**. A true and correct copy of the NIH's July 2025 Notice of Award for T7SS Drug Project is attached as **Exhibit Q**. That Notice of Award authorized funding for two years of work on the T7SS Drug Project, from July 2025 through June 2027, for a total award of $433,125.

19. On August 1, 2025, I received an email from UCLA's Office of Contract & Grant Administration with the subject line "Grant Suspension Notice – Stop Work Order [PATS 20255646]". This email informed me that "UCLA has received a suspension notice from NIH-

NIAID" for the T7SS Drug Project, and notified me that I must "***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***." (emphasis in original). A true and correct copy of this Stop Work Order is attached as **Exhibit R**. NIH's suspension of T7SS Drug Project suspended approximately $429,518 in unfunded award still outstanding to complete T7SS Drug Project's work.

20. I, my team, and the public interest have all suffered harm as a result of the T7SS Drug Project's grant funding suspension. First, we are unable to continue to support the salary component of several people in my laboratory including myself, a co-investigator Professor, and a co-investigator Project Scientist. Additionally, we are unable to support the salary component of a collaborating co-investigator Professor in the high throughput screening facility and his Research Associate. Importantly, we are unable to carry out the high throughput screens of tens of thousands of molecules for their capacity to inhibit the T7SS of *Mycobacterium tuberculosis*, the causative agent of tuberculosis, thereby preventing us from discovering new drugs to treat this very important infectious disease. *M. tuberculosis* kills more people than any other infectious agent and is rapidly developing resistance to currently available drugs. Hence, suspension of this award potentially delays the development of life saving drugs.

I declare under penalty of perjury under the laws of the State of California and the United States that the foregoing is true and correct.

Executed this 20th day of August, 2025, in Los Angeles, California.

Signed by:
Marcus A. Horwitz
C809186107CA45A...

Marcus A. Horwitz